



10-23-06

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Attorney's Docket No.: 17109-012001 / 922

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Rene Gantier et al.  
Serial No. : 10/658,834  
Filed : September 8, 2003  
Cust. No. : 20985  
Title : RATIONAL EVOLUTION OF CYTOKINES FOR HIGHER STABILITY, THE CYTOKINES AND ENCODING NUCLEIC ACID MOLECULES

Art Unit : 1631  
Examiner : Russell Scott Negin  
Conf. No. : 7681

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

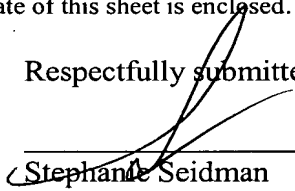
**TRANSMITTAL LETTER**

Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement (2 pages), Form PTO-1449 (4 pages), non U.S. patent cited references, and a return postcard for filing in connection with the above-captioned patent application.

☒ The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

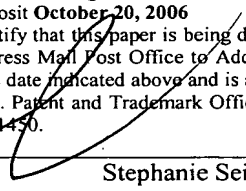
  
Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 17109-012001 / 922

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CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
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Stephanie Seidman



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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

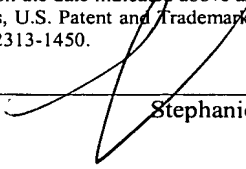
Dear Sir:

Because this Information is provided before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (4 pages) and copies of the cited non-U.S. patent documents are provided herewith in connection with the above-captioned application. Applicant's representative also provides the following International PCT Application:

Serial No.	Filing Date	Publication No.	Publication Date
PCT/US2005/028165	08/08/05	WO 2006/020580	02/23/06

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EV 740123404 US  
Date of Deposit **October 20, 2006**  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

  
Stephanie Seidman

Applicant : Rene Gantier et al.  
Serial No. : 10/658,834  
Filed : September 8, 2003

Attorney's Docket No.: 17109-012001 / 922  
Supplemental Information Disclosure Statement

A copy of published Application No. WO 2006/020580 is provided herewith. The published application is not prior art. It is provided since it appears to incorporate data and information, such as sequences of mutants, provided in the instant application.

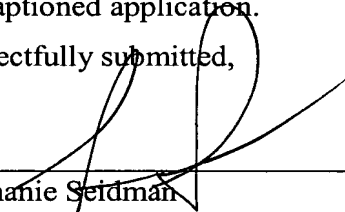
The documents listed on the Form PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed item is necessary.

Since the last Supplemental Information Disclosure Statement was filed on September 26, 2006, no additional co-pending applications need be made known to the Examiner.

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97 (g and h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56 (b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and make them of record in the file history of the above-captioned application.

Respectfully submitted,



---

Stephanie Seidman  
Reg. No. 35,779

Attorney Docket No. 17109-012001 / 922  
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Sheet 1 of 4

Substitute Form PTO 1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17109-012001/922	Application No. 10/658,834
	Applicant Rene Gantier et al.		
	Filing Date September 8, 2003	Group Art Unit 1631	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2004/0002474	1/1/2004	Heinrichs <i>et al.</i>			
	AB	2004/0082026	4/29/2004	DeFrees <i>et al.</i>			
	AC	2004/0219131	11/4/2004	Patten <i>et al.</i>			
	AD	2004/0230040	11/18/2004	Cox, George N.			
	AE	2005/0019871	1/27/2005	Lee <i>et al.</i>			
	AF	2005/0026834	2/3/2005	Cox <i>et al.</i>			
	AG	2005/0058621	3/17/2005	Cox, George N.			
	AH	4,503,035	3/5/1985	Pestka <i>et al.</i>			
	AI	4,678,751	7/7/1987	Goeddel, David V.			
	AJ	4,820,638	4/11/1989	Swetly <i>et al.</i>			
	AK	5,198,345	3/30/1993	Gwynne <i>et al.</i>			
	AL	5,441,734	8/15/1995	Reichert <i>et al.</i>			
	AM	5,460,956	10/24/1995	Reichert <i>et al.</i>			
	AN	5,602,232	2/11/1997	Reichert <i>et al.</i>			
	AO	5,710,027	1/20/1998	Hauptmann <i>et al.</i>			
	AP	6,165,458	12/26/2000	Foldvari <i>et al.</i>			
	AQ	6,204,022	3/20/2001	Johnson <i>et al.</i>			
	AR	6,299,870	10/9/2001	Pestka, Sidney			
	AS	6,300,474	10/9/2001	Pestka, Sidney			
	AT	6,372,218	4/16/2002	Cummins, Joseph M.			
	AU	6,455,253	9/24/2002	Patten <i>et al.</i>			
	AV	6,608,183	8/19/2003	Cox III, George N.			
	AW	6,610,830	8/26/2003	Goeddel <i>et al.</i>			
	AX	6,815,184	11/9/2004	Stomp <i>et al.</i>			
	AY	6,846,844	11/27/2003	Tang, Pingwah			
	AZ	6,897,297	5/24/2005	Pepinsky <i>et al.</i>			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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		Applicant Rene Gantier et al.	
		Filing Date September 8, 2003	Group Art Unit 1631

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	BA	0 051 873 B1	9/27/1989	EP				
	BB	0 146 903 A2	7/3/1985	EP				
	BC	0 240 224 A2	10/7/1987	EP				
	BD	0 625 991 B1	4/28/1999	EP				
	BE	02/085941 A2	10/31/2002	PCT				
	BF	2004/019856 A2	3/11/2004	PCT				
	BG	2004/031352 A2	4/15/2004	PCT				
	BH	2004/074486 A2	9/2/2004	PCT				

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	BI	"Interferon Gamma: Amarillo Biosciences, Inc. and Hayashibara Biochemical Laboratories Broaden Scope of Interferon Gamma Agreement," PR News Wire, <a href="http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&amp;STORY=/www/story/06-15-2000/0001244415&amp;EDATE=">http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&amp;STORY=/www/story/06-15-2000/0001244415&amp;EDATE=</a> (accessed on 10/18/2006), 2 pages.
	BJ	"Low Dose Oral Interferon Alpha- Our Lead Product Candidate," Amarillo Biosciences, <a href="http://www.amarbio.com/03productcandidate.html">http://www.amarbio.com/03productcandidate.html</a> (accessed on 10/18/2006), 2 pages.
	BK	"More Facts on Our Lead Product Candidate – Low Dose Oral Interferon Alpha," Amarillo Biosciences, <a href="http://www.amarbio.com/04.html">http://www.amarbio.com/04.html</a> (accessed on 10/18/2006), 2 pages.
	BL	"Amarillo Biosciences (AMAR) to Receive Patent on Solid Dosage Forms of Interferon; Company Also Obtains Private Funding Through Private Placement," PR News Wire, <a href="http://www.acor.org/drugs/pipeline/news/parsed/7795515.news">http://www.acor.org/drugs/pipeline/news/parsed/7795515.news</a> (accessed on 10/20/2006), 2 pages.
	BM	"LDO-IFNa Ingredients," <a href="http://www.angelfire.com/indie/bdchat/IFNaOfficialRpt.html">http://www.angelfire.com/indie/bdchat/IFNaOfficialRpt.html</a> (accessed on 3/30/2005), 1 page.
	BN	Adolf <i>et al.</i> , "Natural human interferon- $\alpha$ 2 is O-glycosylated," <i>Biochem J.</i> 276: 511-518 (1991)
	BO	Allen, G. and K.H. Fantes, "A family of structural genes for human lymphoblastoid (leukocyte-type) interferon," <i>Nature</i> 287: 408-11 (1980)
	BP	Balk <i>et al.</i> , "Biology of prostate-specific antigen," <i>J Clin Oncology</i> 21:383-391 (2003)
	BQ	Bielharz <i>et al.</i> , "Antiviral and Antiproliferative Activities of Interferon- $\alpha$ 1: The Role of Cysteine Residues," <i>J. Interferon Research</i> 6:677-685 (1986)
	BR	Brod, S.A., "Ingested type I interferon: state of the art as treatment for autoimmunity," <i>Exp Biol Med</i> 227(11):981-8 (2002)

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**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	BS	Brod <i>et al.</i> , "Oral administration of human or murine interferon alpha suppresses relapses and modifies adoptive transfer in experimental autoimmune encephalomyelitis," <i>J Neuroimmunol</i> 58(1):61-9 (1995)
	BT	Déry <i>et al.</i> , "Proteinase-activated receptors: novel mechanisms of signaling by serine proteases," <i>Am. J. Physiol</i> 274:C1429-C1452 (1998)
	BU	Di Marco <i>et al.</i> , "Mutational Analysis of the Structure-Function Relationship in Interferon- $\alpha$ ," <i>Biochem Biophys Res Comm</i> 202: 1445-1451 (1994)
	BV	Fink <i>et al.</i> , "Biological Characterization of Three Novel Variants of IFN- $\alpha$ 13 Produced by Human Placental Trophoblast," <i>Placenta</i> 22: 673-680 (2001)
	BW	Goeddel <i>et al.</i> , "Human leukocyte interferon produced by E. coli is biologically active," <i>Nature</i> 287: 411-416 (1980)
	BX	Hu <i>et al.</i> , "Human IFN- $\alpha$ Protein Engineering: The Amino Acid Residues at Positions 86 and 90 are Important for Antiproliferative Activity," <i>J. Immunol.</i> 167: 1482-1489 (2001)
	BY	Khurshudian, A.V., "A pilot study to test the efficacy of oral administration of interferon-alpha lozenges to patients with Sjogren's syndrome," <i>Oral Surg Oral Med Oral Pathol Oral Radiol Endod.</i> 95(1):38-44 (2003)
	BZ	Lawn <i>et al.</i> , "DNA sequence of a major human leukocyte interferon gene," <i>PNAS</i> 78: 5435-9 (1981)
	CA	Lee <i>et al.</i> , "Interferon- $\alpha$ 2 Variants in the Human Genome," <i>J. Interferon and Cytokine Res.</i> 15: 341-349 (1995)
	CB	Masci <i>et al.</i> , "New and modified interferon alfas: preclinical and clinical data," <i>Curr. Oncol. Rep.</i> 5: 108-13 (2003)
	CC	NCBI Core Nucleotide AY255838
	CD	NCBI Protein AAA00949
	CE	NCBI Protein AAA52715
	CF	NCBI Protein AAA55468
	CG	NCBI Protein AAA55519
	CH	NCBI Protein AAA56191
	CI	NCBI Protein AAA75653
	CJ	NCBI Protein AAA94038
	CK	NCBI Protein AAB56781
	CL	NCBI Protein AAL01040
	CM	NCBI Protein AAP20099
	CN	NCBI Protein AAR45816
	CO	NCBI Protein AAR47404
	CP	NCBI Protein AAR47412

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Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	CQ	NCBI Protein AAW12828
	CR	NCBI Protein CAA00410
	CS	NCBI Protein CAC88666
	CT	NCBI Protein CAD29057
	CU	NCBI Protein CAI94176
	CV	NCBI Protein CAI94186
	CW	NCBI Protein P01563 (SwissProt)
	CX	Nisbet <i>et al.</i> , "Single Amino Acid Substitutions at Conserved Residues of Human Interferon- $\alpha$ Can Effect Antiviral Specific Activity," <i>Biochemistry International</i> 11: 301-309 (1985)
	CY	Palmieri <i>et al.</i> , "Interferon alpha-2b at low doses as long-term antiangiogenic treatment of a metastatic intracranial hemangioendothelioma: a case report," <i>Oncol Rep.</i> 7: 145-9 (2000)
	CZ	Piehler, J. and G. Schreiber, "Mutational and Structural Analysis of the Binding Interface between Type I Interferons and their Receptor Ifnar2," <i>J. Mol. Biol.</i> 294: 223-237 (1999)
	DA	Radhakrishnan <i>et al.</i> , "Zinc mediated dimer of human interferon- $\alpha_{2b}$ revealed by X-ray crystallography," <i>Structure</i> 4: 1453-63 (1996)
	DB	Stennicke, H.R. and G.S. Salvesen, "Catalytic properties of the caspases," <i>Cell Death and Differentiation</i> 6:1054-1059 (1999)
	DC	Streuli <i>et al.</i> , "At Least Three Human Type $\alpha$ Interferons: Structure of $\alpha_2$ ," <i>Science</i> 209: 1343-7 (1980)
	DD	Takayama <i>et al.</i> , "Effects of oral administration of interferon-alpha on antibody production in mice with induced tolerance," <i>J Interferon Cytokine Res.</i> 19(8):895-900 (1999)
	DE	Uzé <i>et al.</i> , " $\alpha$ and $\beta$ Interferons and Their Receptor and Their Friends and Relations," <i>J Interferon and Cytokine Res</i> 15: 3-26 (1995)
	DF	Vogelmeier <i>et al.</i> , "Use of secretory leukoprotease inhibitor to augment lung antineutrophil elastase activity," <i>Chest</i> 110:261S-266S (1996)

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